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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/632,748	08/04/2000	Barbara A. Gilchrest	0054.1087-010	2365

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EXAMINER

GUCKER, STEPHEN

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 06/21/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/632,748

Applicant(s)

GILCHREST ET AL.

Examiner

Stephen Grucker
Elizabeth C. Kemmerer, Ph.D.

Art Unit

1646 1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-32 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1 (in part) and 2, drawn to method of inhibiting epidermal melanocyte of keratinocyte cell loss comprising administering to melanocytes a neurotrophin, classified in class 514, subclass 2, for example.
- II. Claims 1 (in part), 3 and 4, drawn to drawn to method of inhibiting epidermal melanocyte of keratinocyte cell loss comprising administering to melanocytes a pseudo-ligand, classification dependent upon structure of pseudo-ligand.
- III. Claims 5, 9, 13 and 25-32, drawn to peptides, classification dependent upon length and structure of peptides.
- IV. Claim 6 (in part), drawn to method of inducing or maintaining hair growth comprising administering a neurotrophin, classified in class 514, subclass 2, for example.
- V. Claims 6 (in part), 7, 8, 17 (in part), 18-20, 21 (in part), and 22-24, drawn to methods of inducing or maintaining hair growth comprising administering a pseudo-ligand, classification dependent upon structure of pseudo-ligand.

- VI. Claim 10 (in part), drawn to method of maintaining or inducing hair color comprising administering a neurotrophin, classified in class 514, subclass 2, for example.
- VII. Claims 10 (in part), 11 and 12, drawn to method of maintaining or inducing hair color comprising administering a pseudo-ligand, classification dependent upon structure of pseudo-ligand.
- VIII. Claim 14 (in part), drawn to method of inducing or maintaining skin color comprising administering a neurotrophin, classified in class 514, subclass 2, for example.
- IX. Claims 14 (in part), 15 and 16, drawn to method of inducing or maintaining skin color comprising administering a pseudo-ligand, classification dependent upon structure of pseudo-ligand.
- X. Claims 17, 18, 21 and 22 (each in part), drawn to method of treating alopecia areata or male pattern baldness comprising administering nerve growth factor, classified in class 514, subclass 2, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions III and each of II, V, VII and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially

different process of using that product (MPEP § 806.05(h)). In the instant case the peptides can be used to isolate specific binding proteins, or to generate antibodies.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups I, II, and IV-X are directed to methods that are distinct both physically and functionally, and are not required one for the other. Invention I requires administration of a neurotrophin to melanocytes, which is not required by any of the other groups. Invention II requires administration of a ligand-ligand to melanocytes, which is not required by any of the other groups. Invention IV requires administration of a neurotrophin to achieve hair growth, which is not required by any of the other groups. Invention V requires administration of a pseudo-ligand to achieve hair growth, which is not required by any of the other groups. Invention VI requires administration of a neurotrophin to achieve hair color, which is not required by any of the other groups. Invention VII requires administration of a pseudo-ligand to achieve hair color, which is not required by any of the other groups. Invention VIII requires administration of a neurotrophin to achieve skin color, which is not required by any of the other groups. Invention IX requires administration of a pseudo-ligand to achieve skin color, which is not required by any of the other groups. Invention X requires administration of nerve growth factor to treat alopecia areata, which is not required by any of the other groups. Therefore, a search and examination of all of the methods in one patent application would result in an undue

burden, since the searches for the methods are not co-extensive based on the different active agents to be administered or the different patient populations treated.

Each of the following pairs of Inventions are unrelated: III/I; III/IV; III/VI; III/VIII; and III/X . Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together and have different modes of operation. Specifically, the method of each Invention pair does not require the pseudo-ligands of Invention III.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements, and different classification, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention:

IF GROUP I, IV, VI OR VIII IS ELECTED:

- a) nerve growth factor;
- b) neurotrophin-3;
- c) neurotrophin 4/5; or
- d) brain-derived neurotrophic factor.

IF GROUP II, III, V, VII OR IX IS ELECTED:

- a) peptide comprising KGK;
- b) peptide comprising KGA;
- c) SEQ ID NO: 4;
- d) SEQ ID NO: 9; or
- e) SEQ ID NO: 10.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is an example of a generic claim.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

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the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker, Ph.D., whose telephone number is (703) 308-6571.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, Ph.D., can be reached on (703) 308-4623. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Elizabeth C. Kemmerer

ECK
June 21, 2002

ELIZABETH KEMMERER
PRIMARY EXAMINER